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Evaluating the Role of Genetic Markers in Prostate Cancer Progression: A Multiethnic Cohort Experience

PRINCIPAL INVESTIGATOR:
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<p>14. ABSTRACT Most prostate cancer (PCa) research has focused on risk, little is known about predictors of progression and even less about how these factors differ by ethnicity/race. Strong racial disparities in mortality have shown that African-Americans are twice as likely to die from PCa compared to Caucasians; very little data are available in Hispanics. Our overall goal is to identify markers related to PCa progression in a multiethnic cohort of 773 Caucasians, 361 African-Americans, and 246 Mexican-Americans, for whom we have already collected information. We have abstracted medical records for 735 patients and are now requesting copies of outside medical records for those who received care outside our institution, as well as continuing to abstract medical records. Additionally, we are preparing a request for vital status from the National Death Index to obtain information on cause of death. Genotyping assays have been established in the Genotyping Core, and DNA has been extracted from 90% of the patients' blood. Our research may help explain ethnic/racial disparities in PCa progression and provide direction towards eliminating these disparities and may guide future studies to develop ethnic/racial specific interventions to improve outcome in the most common cancer in American men.</p>							
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INTRODUCTION:

There is a paucity of information regarding markers/factors associated with prostate cancer (PCa) outcome in the United States, especially how these factors differ among racial/ethnic groups. African-American men are more likely to have poorer outcome relative to age and stage-matched Caucasian patients; and very little is known about prognosis and even less about factors that could predict progression among Hispanics. The overall goal of our research project is to identify molecular, epidemiological and clinical markers related to prostate cancer (PCa) progression in a multiethnic cohort of 1,380 PCa patients (773 Caucasians; 361 African Americans, and 246 Mexican Americans).

BODY:

Task 1 Patient Follow-up. (Months 1-30)

- a. Update patient follow-up data by checking clinical schedules and medical charts for updated information. Using a validated medical abstraction form, all patient charts will be abstracted.
- b. Signed medical releases of information will be requested for care received outside of our institution. Copies of medical records will be requested.
- c. Death certificates will be obtained for all participants identified as deceased.
- d. Patients' self-reported recurrences (and subsequent treatments) and secondary cancers will be verified.
- e. Data will be entered into existing databases.

In the first year of this grant, we have completed medical record abstractions for 735 prostate cancer patients who have received follow-up care at our institution. Institutional patient records for each participant are being abstracted using the standardized form attached as Appendix A. The most recent clinical follow-up date at our institution is determined; this date is used as the "last date of contact" at the University of Texas MD Anderson Cancer Center (UTMDACC). In addition to baseline treatment information, we abstracted follow-up information, such as each prostate specific antigen (PSA) level and date, adjuvant care received, prostate-related care (including care related to complications following treatment (i.e., incontinence, impotence)), as well as additional cancer diagnoses. Institutional medical records are available electronically, and abstractions are performed using a paper form and are being entered into an existing clinical database. We are continuing to abstract institutional medical records for the remainder of the patients.

For patients for whom we do not have recent follow-up information at UTMDACC, we are conducting telephone interviews to request follow-up information. One of the greatest challenges we have faced has been in locating and contacting these individuals as several years have passed since we last spoke with them. We have explored several options for obtaining updated contact information; including general internet searches, reverse address searches, and credit records. The Acxiom Insight Collection service, which is an internet-based paid subscription database, has been the most useful tool for us. To-date, we have successfully completed 75 follow-up interviews by phone. The protocol to verify potentially valid contact information includes calling the individual at least 5 times at different times of the day, as well as on weekends, if needed; the calls are conducted using the telephone script included as Appendix B. In addition, if these call attempts are not successful, then we send a letter to the patient at the last known valid address (with address correction requested) explaining that we are trying to contact them regarding their follow-up in a study and requesting that they contact us at their earliest convenience. Updated health and risk factor information is collected by trained interviewers, using a standardized questionnaire modified for this project (Appendix C).

Patients who are receiving follow-up care outside of UTMDACC are asked to sign a medical record release form (Appendix D) to allow us to obtain copies of the relevant records from their healthcare providers. Outside medical records are abstracted using the same standardized forms as used for UTMDACC records. Clinical recurrences and related treatments are noted on the abstraction forms and verified by the study clinical personnel.

We are preparing the Centers for Disease Control Institutional Review Board application to obtain approval to request vital status from the National Death Index, as well as immediate and underlying causes of death for deceased individuals.

Task 2 Evaluate Constitutional Markers of Genetic Susceptibility. (Months 1-30)

- a. Genotyping assays for all genes will be established, tested and validated by the Department of Epidemiology Genotyping Core (Months 1-24).
The necessary laboratory equipment has been calibrated and tested. The primers and reagents have been purchased and quality-control tested. Conditions for all the genes proposed have been optimized on a test set available in the lab.

- b. Biological samples for all participants will be located and retrieved from study archive freezers (Months 1-3).
Using our laboratory tracking database, biological samples for this study have been identified, located and retrieved from our freezer facility. Samples that will be used have been mapped and transferred to the genotyping facility. All

specimens are currently stored at -80° in the on-site freezers until analyses are conducted.

- c. DNA will be extracted from banked specimens (Months 1-12).
DNA has been extracted from 90% of banked specimens; the remainder are expected to be completed within the next 30 days. DNA quality has been tested for the extracted samples to ensure the success of the analyses.

- d. DNA samples will be plated for genotyping analyses – half the samples will be done in Year 2 and the other half will be done in Year 3 (Months 13 & 25)

N/A

- e. Genotyping will be done for half the samples in Year 1 (Months 13-24) and the other half in Year 2 (Months 25-30).

N/A

Task 3

Final Analysis and Preparation of Reports. (Months 30-36) –

N/A

KEY RESEARCH ACCOMPLISHMENTS:

There are no key research accomplishments to report at this time; we are still in the process of collecting follow-up data. No interim analyses have been performed, nor were any planned to be conducted at this time-point.

REPORTABLE OUTCOMES:

Currently, there have been no manuscripts, abstracts, presentations, patents or licenses applied for based on this award. Additionally, there have not been any degrees supported by this award; no cell lines, tissue or serum repositories developed; no informatics nor funding applied for based on work from this award; no employment nor research opportunities applied for and/or received based on experience/training supported by this award.

CONCLUSION:

Our research may help explain ethnic/racial disparities in PCa progression and provide direction towards eliminating these disparities. Additionally, our results may guide future studies to develop ethnic/racial specific interventions (i.e., behavioral, clinical) to improve outcome in the most common cancer in American men.

REFERENCES: N/A

APPENDICES:

APPENDIX A:

Medical record abstraction form

Medical Records Abstraction Form

Name

MDACC# _____

MDA registration date ____/____/____

Address

Date of birth ____/____/____

Age at diagnosis _____ years

Phone number _____

Ethnicity

White
 Hispanic
 African-American
 Asian
 Other _____

→

Mexican
 Cuban
 S. American
 Other _____

Vital status

Living

Deceased → Date of death ____/____/____

Place of death _____

Cause of death _____

Last date of contact ____/____/____

Place of contact _____

Height: _____ cm
_____ ft/inches

Weight: _____ kg
_____ lbs

Prostate cancer diagnosis

Date of diagnosis ____/____/____

Place of diagnosis: MDACC

Yes

No

Diagnostic tests Biopsy POS NEG

↓ Where _____

TURP POS NEG

Chest x-ray POS NEG

Bone scan POS NEG

CT scan POS NEG

Other _____ POS NEG When ____/____/____

Comments _____

Clinical stage of diagnosis

Organ confined disease

Regional disease

Metastatic disease → date of confirmation ____/____/____

Sites: Bones Liver Adrenal gland Kidney Brain

Other _____

TNM stage

T1 → x 0 a b c **T2** → a b c **T3** → a b **T4**

N → x 0 1 2 3

M → x 0 1 Summary _____

Comments _____

Laboratory results

Post-treatment values

Most recent post-treatment PSA value _____ ng/ml Date ____/____/____

Follow-up PSA Values _____ ng/ml Date ____/____/____

Initial post-treatment PSA value _____ ng/ml Date ____/____/____

Pre-treatment values

Highest pre-treatment PSA value _____ ng/ml Date ____/____/____

Initial pre-treatment PSA value _____ ng/ml Date ____/____/____

Comments: _____

Pathology report**Pathology report #:** _____

Specimen type

Prostatectomy

MDACC grade <= I II III IV other _____**Seminal Vesicle involvement** Yes NoS/Margins Positive Negative**Combined Gleason score**

2 3 4 5 6 7 8 9 10 _____

Dominant focus size /size _____ cm Prostate volume _____ cm

Tumor locations Peripheral zone Central zone Transitional zone AFM zone

Comments _____

Pathology report**Pathology report #:** _____Specimen type <= **Biopsy**MDACC grade <= I II III IV other _____

Combined Gleason score

2 3 4 5 6 7 8 9 10

Dominant focus size /size _____ cm Prostate volume _____ cm

Tumor locations Peripheral zone Central zone Transitional zone AFM zone

Comments _____

History of prostate cancer screening No Yes → Type of screening test Prostate-specific antigen (PSA) Digital rectal examination (DRE) Trans-rectal ultrasound (TRUS) Other _____Presence of urinary symptoms Yes No

Comments: _____

Prostate cancer treatment received

Radical prostatectomy Type → Radical Retropubic Prostatectomy (RRP) Date ____/____/____
 Radical perineal prostatectomy (RPP)
 Nerve-sparing
 Pelvic lymphadenectomy

Orchietomy → Date ____/____/____

Cryosurgery → Date ____/____/____

	<u>Onset of treatment</u>	<u>End of treatment</u>
<input type="checkbox"/> Radiotherapy (EBRT)	→ Date ____/____/____	Date ____/____/____
<input type="checkbox"/> Brachytherapy	→ Date ____/____/____	Date ____/____/____
<input type="checkbox"/> Hormonal therapy	→ Date ____/____/____	Date ____/____/____
<input type="checkbox"/> Immunotherapy	→ Date ____/____/____	Date ____/____/____
<input type="checkbox"/> Surveillance	→ Date ____/____/____	Date ____/____/____
<input type="checkbox"/> Chemotherapy	→ Date ____/____/____	Date ____/____/____
<input type="checkbox"/> Other (specify) _____	Date ____/____/____	Date ____/____/____

Comments _____

Complications of treatment

Urinary
Incontinence No
 Yes → Uses sanitary pad No
 Yes → number /day _____

Treatment received _____

Post-treatment status (1yr.) Number of pads/day _____ Date ____/____/____

Impotence No
 Yes → Treatment received _____

Post-treatment status (1yr.) _____

Urinary retention No
 Yes Treatment received _____

Other _____

Comorbid conditions prior to diagnosis of prostate cancer

No Yes



- Diabetes (IDDM, NIDDM) Date of diagnosis ____/____/____
- Hemorrhage Date of diagnosis ____/____/____
- Hypertension Date of diagnosis ____/____/____
- Peptic ulcer disease Date of diagnosis ____/____/____
- Congestive heart failure Date of diagnosis ____/____/____
- Pancreatitis Date of diagnosis ____/____/____
- Myocardial infarction Date of diagnosis ____/____/____
- Cholelithiasis Date of diagnosis ____/____/____
- Stroke Date of diagnosis ____/____/____
- Alcoholism Date of diagnosis ____/____/____
- Chronic obstructive pulmonary disease Date of diagnosis ____/____/____
- Lupus erythematosus Date of diagnosis ____/____/____
- Other _____ Date of diagnosis ____/____/____

Other pertinent informationRecurrence of prostate cancer

No
 Yes → Date of diagnosis ____/____/____

Place of diagnosis _____

Type of treatment _____

Basis of diagnosis _____

Diagnostic tests Biopsy POS NEG
 TURP POS NEG
 Chest x-ray POS NEG
 Bone scan POS NEG
 CT scan POS NEG
 Other _____ POS NEG

Conditions diagnosed after diagnosis of prostate cancer

No

Yes



Date of diagnosis ____/____/____
Type of disease _____

Date of diagnosis ____/____/____
Type of disease _____

Place of diagnosis _____
Type of treatment received_____

Place of diagnosis _____
Type of treatment received_____

Comments _____

Last clinic visit

Date ____/____/____

Notes

APPENDIX B:

Follow-up telephone recruitment script

SCRIPT 1 (Speaking to person who answers phone) –

Hello, my name is (INTERVIEWER'S NAME) and I am calling on behalf of MD Anderson Cancer Center, here in Houston. May I please speak with (PATIENT'S NAME)?

- NOT AVAILABLE – Verify (PATIENT'S NAME) lives at this residence. Ask "Is there a time that I could call back and speak with him?" OR "would you please ask him to call me (INTERVIEWER'S NAME) at (PHONE NUMBER) at his earliest convenience? Thank you for your assistance.
- YES – Thank you...(Wait for (PATIENT'S NAME) come to phone) Hello, my name is (INTERVIEWER'S NAME) and I am calling on behalf of MD Anderson Cancer Center, here in Houston. You participated in one of our prostate cancer studies a few years ago, and we are conducting a follow-up study to see how you are doing. Would it be all right with you if I asked you a few questions about your health and updated your information?
 - NO – thank you for your time. If you change your mind and would like to participate, please contact me (INTERVIEWER'S NAME) at (PHONE NUMBER).
 - YES – I want to let you know that answering these questions is completely voluntary, and you may decide not to answer any or all of them. (Administer risk factor questionnaire (Appendix D))

Following each call, the interviewer logs each call made onto the tracking log for each file, documenting the date, time, phone number dialed, and with whom they spoke. These logs are maintained in the individual patient's study chart, kept in a locked office coded by study identification number.

APPENDIX C:
Follow-Up questionnaire

PROSTATE CANCER FOLLOW-UP STUDY

M.D. A

M.D. Anderson Cancer Center

Department of Epidemiology

STUDY NUMBER: _____

DATE OF PC DIAGNOSIS: ____ / ____ / ____

MED RECORD/PATIENT #: _____

DATE OF BASELINE INTERVIEW: ____ / ____ / ____

PATIENT RECEIVING FOLLOW-UP CARE AT MDACC: (1) YES
(2) NO

DATE OF MOST RECENT MDACC VISIT: ____ / ____ / ____

FIRST NAME _____ **M.I.** _____ **LAST NAME** _____

HOME PHONE: (____) _____

STREET ADDRESS _____

WORK PHONE: (____) _____

CITY _____ **STATE** _____ **ZIP CODE** _____

SSN: _____

INTERVIEW DATE: ____ / ____ / ____

INTERVIEWER'S INITIALS: _____

WHO IS COMPLETING QUESTIONNAIRE? **PATIENT**

PROXY

IF PATIENT IS DECEASED, DATE OF DEATH _____

COUNTY & STATE OF DEATH _____

As you may remember, you participated in a study of prostate cancer. We are currently updating our information, and we wanted to see how you are doing. Do you have a few moments to talk to me now or when can I call you back?

1. Are you currently being followed-up for your previous prostate cancer? _____ YES (1) _____ NO (2)

2. Where are/were you receiving follow-up care? _____

3. When was your most recent follow-up visit? _____ (Date)

When was the last time you had (the following test(s))? What were the results?

Test	Most Recent Date	Result (most recent)
4. Prostate Specific Antigen/ (PSA)		<input type="checkbox"/> Normal (1) go to Q.8 <input type="checkbox"/> Abnormal (2) go to Q.5
5. Ultrasound (TRUS)		
6. Biopsy or Transurethral Resection of Prostate (TURP)		
7. Other (specify)		

8. Have you received any prostate treatment since you were last seen at MD Anderson/Kelsey-Seyboldt/VAMC/Dr.

_____ (select provider) in _____ (fill in last date)?

(1)YES (2) NO → Skip to Q. 12

9. When and where were/are you receiving treatment? (e.g., MD/Clinic Name, Address, Phone #)

Office Note: Obtain signed medical release of information

10. What type(s) of treatment did you receive? (e.g., radiation, hormone shots, hormone pills, chemotherapy)

11. Why was the treatment necessary?

Have you ever been told by a doctor or another health care professional that you have any of the following conditions?

CONDITION	BEEN TOLD? <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO	DATE/AGE DIAGNOSED	TREATMENT/MEDICATION NAME
12. Diabetes (or sugar in urine)	<input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO		
13. Hypertension (high blood pressure)	<input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO		
14. Angina (angina pectoris)	<input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO		
15. Heart attack (myocardial infarction)	<input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO		
16. Any other kind of heart condition or disease (not mentioned above) SPECIFY: _____	<input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO		

CONDITION	BEEN TOLD?	DATE/AGE DIAGNOSED	TREATMENT/MEDICATION NAME
17. High cholesterol	<input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO		
18. Arthritis TYPE: _____	<input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO		
19. Any other cancer(s)? SPECIFY	<input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO		
20. Any other condition(s)? SPECIFY	<input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO		

TOBACCO

Previous Smoking Status

Current Former Never

The next questions are about smoking.

21. Since your prostate cancer diagnosis, has your smoking status changed? (1) YES (2) NO →

Fmr/Never smkr Go to Q.24
Currt smkr Go to Q.23

22. Are you currently smoking cigarettes? (1) YES (2) NO → When did you stop? _____ (Year)

23. On average, how many cigarettes per day do you/did you smoke? _____

MEDICATION/SUPPLEMENT USE

The next questions are medications and supplement use

24. Have you taken any supplements, over the counter medications or prescription medications at least once a month since your diagnosis? This would include all vitamins, minerals, herbal and non-herbal supplements of any kind.

(2) No, GO TO Q. 26

(1) Yes, Fairly regularly

(3) Yes, but NOT regularly

25. Please list the names of any supplements (including vitamins, minerals and herbal supplements), over-the-counter medications or prescription medications that you have taken. Also include the number of pills or tablets taken daily, weekly, monthly or yearly?

For Office Use:	<input type="text"/> code						
Supplement, Over-the-counter or prescription medication	Number per Day	Number per Week	Number per Month	Number per Year	Rarely / Never (✓)	How many years?	Dose
Brand: _____ Name on bottle: _____							
Brand: _____ Name on bottle: _____							
Brand: _____ Name on bottle: _____							
Brand: _____ Name on bottle: _____							

DIET

The following questions are regarding diet changes

Since your diagnosis, have you changed your consumption of the following types of foods?

FOOD TYPE	INCREASED
26. Fat	<input type="checkbox"/> (1) increased <input type="checkbox"/> (2) decreased <input type="checkbox"/> (3) no change
27. Fruits	<input type="checkbox"/> (1) increased <input type="checkbox"/> (2) decreased <input type="checkbox"/> (3) no change
28. Vegetables	<input type="checkbox"/> (1) increased <input type="checkbox"/> (2) decreased <input type="checkbox"/> (3) no change
29. Fiber	<input type="checkbox"/> (1) increased <input type="checkbox"/> (2) decreased <input type="checkbox"/> (3) no change
30. Soy products	<input type="checkbox"/> (1) increased <input type="checkbox"/> (2) decreased <input type="checkbox"/> (3) no change

31. Are there any comments that you would like to add about your diet or about the way you have changed your diet?

FAMILY HISTORY

In this section, I would like to ask you some questions about your family

+

FAMILY HISTORY PRE-CODE:

Previously reported family members WITH cancer:

Sex	Relative	Side of Family	Type of Cancer	Sex	Relative	Side of Family	Type of Cancer

32. Previously, you told us that your _____ (insert previous history here) had cancer, have any other immediate family members been diagnosed with cancer? YES (1) NO (2) → Go to Q. 34

33. Would you please give us some information about these NEW family members diagnosed with cancer? (DON'T include those previously reported)

Rel Code	Sex	Relative	Rel UIN	When was he/she born?	What kind of cancer? ICD-9	When was he/she diagnosed?	Is he/she still living?	When did he/she die?
							<input type="checkbox"/> (1) Yes <input type="checkbox"/> (2) No	
							<input type="checkbox"/> (1) Yes <input type="checkbox"/> (2) No	
							<input type="checkbox"/> (1) Yes <input type="checkbox"/> (2) No	
							<input type="checkbox"/> (1) Yes <input type="checkbox"/> (2) No	
							<input type="checkbox"/> (1) Yes <input type="checkbox"/> (2) No	

OCCUPATIONAL HISTORY

34.

In this section, I would like to ask you some questions about your current occupation

What is your job or occupation?	Years employed	Major duties	Equipment used (Any Chemicals?)	Work done by company	SIC	OCC
Current Job:	____ To _____					
Spec						

If we need additional information from you in the future, can we contact you by telephone? (1)YES (2)NO

This is the end of our interview. I would like to thank you for your help with our research. If you have any questions that I or Dr. Strom can answer in the future, please feel free to contact us. We would also like to verify that we have your current address correctly recorded. We have your current address as: **READ ADDRESS FROM FILE RECORD**

Is this address correct? (1) YES (2)NO (*If NO, please provide correct information below*)

First Name

Middle Name

Last Name

Street Address

City

State

Zip Code

Also, so that we may keep contact with you, would you please give me that name, address, and telephone number of a person who does not live with you who will know your whereabouts in the future:

First Name

Middle Name

Last Name

Street Address

City

State

Zip Code

Thank you once again for your time and help with our research project. If we have any more questions in the future, we hope we can call you again.

INTERVIEW ASSESSMENT

Date of interview: ____ / ____ / ____

Interviewer's Initials: _____

Time Interview began: _____

Time Interview ended: _____

1. Respondent's cooperation was:

Very Good (1)

Good (2)

Fair (3)

Poor (4)

2. The quality of the interview was:

Highly Reliable (1)

Generally Reliable (2)

Questionable (3)

Unsatisfactory (4)

Please write comments about the interview: _____

APPENDIX D:
Medical release of information form

AUTHORIZATION FOR DISCLOSURE OF HEALTH INFORMATION

(1) I hereby authorize _____ to disclose the following information from the health records of:

Patient Name: _____
Last _____ First _____ MI. _____ Date of Birth _____ MDA # _____

Address: _____

Street _____ City _____ State _____ Zip Code _____
Phone _____

covering the period of healthcare from _____ to _____.

(2) Information to be disclosed:

- | | |
|---|---|
| <input type="checkbox"/> Complete Health Record | <input type="checkbox"/> Consultation Reports |
| <input type="checkbox"/> Primary Medical Evaluation | <input type="checkbox"/> Laboratory Tests |
| <input type="checkbox"/> Progress Notes | <input type="checkbox"/> Radiotherapy Notes |
| <input type="checkbox"/> X-Ray Reports | <input type="checkbox"/> Chemotherapy Notes |
| <input type="checkbox"/> Discharge Summary | <input type="checkbox"/> Nurse's Notes |
| <input type="checkbox"/> Other (specify) _____ | |

I understand that this will include information relating to (check if applicable):

- | |
|---|
| <input type="checkbox"/> Acquired Immunodeficiency Syndrome (AIDS) or infection with HIV (Human Immunodeficiency Virus) |
| <input type="checkbox"/> Psychiatric care |
| <input type="checkbox"/> Treatment for alcohol and/or drug abuse |

(3) This information is to be disclosed to: Dr. Sara Strom



Investigator's signature

UT MD Anderson Cancer Center

1515 Holcombe, Houston, Texas 77030

for the purpose of: **Medical Record completion for research protocol M91-004.**

- (4) I understand this authorization may be revoked in writing at any time, except to the extent that action has been taken in reliance on this authorization. Unless otherwise evoked, this authorization will expire on the following date, event, or condition:

(5) The facility, its employees, officers, and physicians are hereby released from any legal responsibility or liability for disclosure of the above information to the extent indicated and authorized herein.

SUPPORTING DATA: N/A